**Site visit inspection report on compliance with HTA licensing standards**

**John Radcliffe Hospital**

**HTA licensing number 12217**

**Licensed under the Human Tissue Act 2004 for the**

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

**4-6 June 2019**

**Summary of inspection findings**

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the John Radcliffe Hospital (the establishment) was found to have met the majority of the HTA standards, three minor shortfalls were identified relating to Governance and quality systems, Traceability and Premises, facilities and equipment standards.

The DI has also been given advice on a number of areas in relation to consent training records, governance/documentation and storage matters.

## The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

**Background to the establishment**

This report refers to activities carried out at the John Radcliffe Hospital (the 'establishment'). The establishment is licensed for the storage of relevant material that has come from a human body for use for a scheduled purpose, under the Human Tissue Act 2004 (HT Act). Human samples are stored for use for the scheduled purposes of 'research in connection with disorders, or functioning, of the human body' and 'education or training relating to human health'.

The establishment has been licensed since June 2007 and this was the third routine site-visit inspection to assess whether it continues to meet the HTA's standards.

The licence covers the hub site at the John Radcliffe Hospital, and four satellite premises located at the Churchill Hospital, the Nuffield Orthopaedic Centre, the University of Oxford Pharmacology Building and the Medawar Building. The Medawar building has been added as a satellite since the last inspection in January 2019.

Under the licence, there are human tissue research collections as well as eight research tissue banks (RTBs): Oxford Brain Bank (15/SC/0639), Oxford Musculoskeletal Biobank (19/SC/0134), Quality in Organ Donation Biobank (18/NW/0187), Oxford Transplant Biobank (14/SC1211), Oxford Radcliffe Biobank (19/SC/0173), Pancreatic Cancer Research Fund Tissue Bank (13/SC/0593), Oxford Vaccine Centre Biobank (16/SC/0141) and Oxford GI Illness Biobank (16/YH/0247). The establishment has some projects that have approval from recognised research ethics committees (RECs) and stored relevant material is therefore exempt from the licensing requirements of the HT Act. However there is a system in place to identify when the approvals will expire and when samples will then be transferred under the governance of the licence.

There is a robust governance structure to ensure oversight of all collections. Principal Investigators (PIs) are directly responsible for the day to day running of the RTBs and collections, and Collection Responsible Officers oversee compliance and monitor activity. There are Persons Designated (PDs) named on the licence and a Human Tissue (HT) Governance Team has oversight of all activities and is directly reportable to the Designated Individual (DI). The DI is the lead for Clinical Biochemistry, the Corporate Licence Holder (CLH) is the Chancellor, Masters and Scholars of the University of Oxford and the CLH contact (CLHc) is the Head of Commercial Strategy and Risk for the Medical Sciences Division. Both the DI and the CLHc have been newly appointed since the last inspection.

The majority of storage locations are secured in designated laboratory areas although two freezers containing relevant material were situated within a patient waiting area (see shortfall against standard PFE1 (a)). All freezers are fitted with automated alarms that are triggered by deviations from the set acceptable temperature ranges. Relevant staff are alerted when

alarms are triggered (see *Advice*, item 5). Two fridges storing relevant material were not connected to the alarm system; however, the HTA was assured that the temperature was not critical for sample integrity (see *Advice*, item 6). All rooms containing liquid nitrogen storage tanks are secure and fitted with oxygen monitoring systems. As well as back-up power supplies, the establishment has contingency arrangements for all temperature-controlled storage.

There are overarching governance documents across all collections which includes Standard Operating Procedures (SOPs) and risk assessments (see *Advice*, item 2). Local documents were also available detailing specific procedures relating to the collections.

For the samples in the RTBs, patients and volunteers are contacted and given relevant documentation including an information sheet. Once the participant agrees to take part, consent is sought by trained staff using an appropriate consent form. After samples are obtained, they are given a unique identification number and patient files are de-identified. Each RTB has their own database that records the identification number and relevant sample details. The RTBs provide a resource for researchers and there is an application process including an assessment by a committee before samples are approved to be sent out for research. For projects outside of RTBs, and for imported collections and/or collections making use of existing samples, there is a review of the project by the University ethics committee before material is obtained. Material is obtained by trained individuals using specific information sheets and consent forms, or from other establishments with material transfer agreements in place, including from overseas. Each collection has their own database that records the identification number and relevant sample details.

**Description of inspection activities undertaken**

The inspection timetable was developed in consideration of the activities conducted under the licence, compliance update information, discussions with the DI, communications with the HTA and the findings of the previous inspection. The inspection included review of the establishment's procedures for conducting activities under the licence and discussions with staff responsible for the RTBs and collections. The inspection also included a visual inspection of the areas where samples were stored and audits of sample traceability.

Audits of 42 randomly-selected samples were conducted from seven of the eight RTBs as well as seven other collections. Samples were chosen from all storage locations including liquid nitrogen tanks, fridges, freezers and room temperature areas. Audits covered sample location, documentation, tracking systems, disposal records, consent documentation or MTAs and consent-seekers training records.

All samples were fully traceable although one individual collection had an inventory of boxes but not a register of material that was in the box (see shortfall against standard T1 (b)).

**Compliance with HTA standards**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
| c) Staff can access risk assessments and are made aware of risks during training. | Although there are core risk assessments for all processes and practices requiring compliance with the HT Act and HTA's Codes of Practice, there is no reference to them in the individual biobanks/ collections documentation. As a result not all staff are aware of them. | **Minor** |
| **T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail** | | |
| b) A register of donated material, and the associated products where relevant, is maintained. | During the traceability audit one collection had an inventory of boxes but no information on the contents or number of samples within the box. | **Minor** |
| **PFE1 The premises are secure and fit for purpose** | | |
| a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. | The floor in a laboratory containing the cryostore was in poor condition with the lifting of the floor covering causing a safety hazard.<br>Two freezers containing relevant material were situated within a patient waiting area. Although locked,the power supply was not protected. | **Minor** |

## Advice

The HTA advises the DI to consider the following to further improve practices:

| No. | Standard | Advice |
|---|---|---|
| 1. | C2(b) | All consent seekers had up-to-date training records. The DI is advised to keep the record of consent seekers most up-to-date training with the consent delegation logs. |
| 2. | GQ1(a) | The establishment has recently started using a new quality management software system. The DI is advised to continue to roll this system out to all groups and collections under the licence. |
| 3. | GQ1(a) | The Quality in Organ Donation biobank SOP008 on Disposal references the old HTA Code of Practice on Disposal. The DI is advised to update this reference with the Code of Practice E, Research, which details disposal requirements. |
| 4. | GQ6(a) | There are future plans to demolish a building adjacent to the Pharmacology and Medawar buildings. This may restrict liquid nitrogen delivery to the two |

| | | |
|---|---|---|
| | | satellite premises. The DI is advised to assess the relevant risks and ensure that plans are in place to ensure the cryostorage of relevant material is not compromised during the works. |
| 5. | PFE2(c) | All of the temperature-monitored freezers have external alarm and call-out systems and some of the RTBs challenge test these systems. The DI is advised to challenge all alarm systems to ensure that when temperature deviations are detected, the system operates successfully. The DI is also advised to review temperature trends. |
| 6. | PFE2(c) | There were two, standalone fridge units containing human material that were not alarmed. Although refrigerated storage conditions were not critical as material was fixed, the DI is advised to ensure all temperature controlled units storing relevant material are monitored, maintained and deviations in storage conditions acted on when required. |

**Concluding comments**

This report outlines the third, routine HTA site visit inspection of the John Radcliffe Hospital.

Although there are areas of practice that require improvement, including three minor shortfalls, the HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

**Report sent to DI for factual accuracy: 25 June 2019**

**Report returned from DI: 05 July 2019**

**Final report issued: 26 July 2019**

**Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 26 November 2019**

## Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

| Consent standards |
| --- |
| **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice** |
| a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.<br>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.<br>c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.<br>d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.<br>e) Language translations are available when appropriate.<br>f) Information is available in formats appropriate to the situation. |
| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** |
| a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.<br>b) Records demonstrate up-to-date staff training.<br>c) Competency is assessed and maintained. |

| Governance and quality system standards |
| --- |
| **GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process** |
| a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.<br>b) There is a document control system.<br>c) There are change control mechanisms for the implementation of new operational procedures.<br>d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.<br>e) There is a system for managing complaints. |
| **GQ2 There is a documented system of audit** |
| a) There is a documented schedule of audits covering licensable activities.<br>b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these. |

| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills** |
|---|
| a) Qualifications of staff and all training are recorded, records showing attendance at training. |
| b) There are documented induction training programmes for new staff. |
| c) Training provisions include those for visiting staff. |
| d) Staff have appraisals and personal development plans. |
| **GQ4 There is a systematic and planned approach to the management of records** |
| a) There are suitable systems for the creation, review, amendment, retention and destruction of records. |
| b) There are provisions for back-up / recovery in the event of loss of records. |
| c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing). |
| **GQ5 There are systems to ensure that all adverse events are investigated promptly** |
| a) Staff are instructed in how to use incident reporting systems. |
| b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made. |
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** |
| a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. |
| b) Risk assessments are reviewed regularly. |
| c) Staff can access risk assessments and are made aware of risks during training. |

| **Traceability standards** |
|---|
| **T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail** |
| a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. |
| b) A register of donated material, and the associated products where relevant, is maintained. |
| c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom. |
| d) A system is in place to ensure that traceability of relevant material is maintained during transport. |
| e) Records of transportation and delivery are kept. |
| f) Records of any agreements with courier or transport companies are kept. |
| g) Records of any agreements with recipients of relevant material are kept. |

| T2 Bodies and human tissue are disposed of in an appropriate manner |
|---|
| a) Disposal is carried out in accordance with the HTA's Codes of Practice. |
| b) The date, reason for disposal and the method used are documented. |

| Premises, facilities and equipment standards |
|---|
| **PFE1 The premises are secure and fit for purpose** |
| a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. |
| b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. |
| c) There are documented cleaning and decontamination procedures. |
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue** |
| a) There is sufficient storage capacity. |
| b) Where relevant, storage arrangements ensure the dignity of the deceased. |
| c) Storage conditions are monitored, recorded and acted on when required. |
| d) There are documented contingency plans in place in case of failure in storage area. |
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** |
| a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. |
| b) Users have access to instructions for equipment and are aware of how to report an equipment problem. |
| c) Staff are provided with suitable personal protective equipment. |

## Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

**1. Critical shortfall:**

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

*or*

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

**2. Major shortfall:**

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

*or*

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

**3. Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure

from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

## Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.